THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte C. MICHAEL JONES

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Appeal No. 1996-0848
Application 07/624,053

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ON BRIEF

_____

Before WINTERS, DOWNEY, and ROBINSON, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 16-22, 24-25, 27-32, 34-35, and 42, all of the claims pending in the application. Claims 22, 25, and 42 are illustrative of the claims on appeal and read as follows:

22. A continuous cell line producing a human monocyte cytotoxicity inducing factor, the factor characterized by the following properties:

(a) capability of inducing human monocytes to a cytotoxic state;

(b) retention of biological activity following treatment at pH 2 for one hour;

(c) retention of biological activity following treatment at 60 ºC for one hour;

(d) ability to bind to Matrex Gel Red A under low-salt conditions and elute from Matrex Gel Red A under high-salt conditions; and

(e) retention of biological activity in the presence of antiserum to interferon gamma, interferon alpha, or a combination of anti-sera to interferon alpha and gamma.

25. A continuous cell line which produces a factor capable of inducing human monocytes to a cytotoxic state, the continuous cell line being produced by a process comprising the steps of:

(a) immortalizing human T-cells to produce continuous cell clone;

(b) identifying a clone which produces a human monocyte cytotoxicity inducing factor having the following properties:

i) capability of inducing human monocytes to a cytotoxic state;

ii) retention of biological activity following treatment at pH 2 for one hour;

iii) retention of biological activity following treatment at 60 ºC for one hour;

iv) ability to bind to Matrex Gel Red A under low-salt conditions and elute from Matrix Gel Red A under high-salt conditions; and

v) retention of biological activity in the presence of anti-serum to interferon gamma, interferon alpha, or a combination of anti-sera to interferon alpha and gamma; and

(c) culturing the clone to produce the continuous cell line.

42. A method of generating a continuous cell line which produces a factor capable of inducing human monocytes to a cytotoxic state, the method comprising the steps of:

(a) immortalizing human T-cells to produce continuous cell clones;

(b) identifying a clone which produces a factor having the following characteristics:

i) capability of inducing human monocytes to a cytotoxic state;

ii) retention of biological activity following treatment at pH 2 for one hour;

iii. retention of biological activity following treatment at 60$^{\beta}$ C for one hour;

iv. ability to bind to Matrex Gel Red A under low-salt conditions and elute from Matrex Gel Red A under high-salt conditions; and

v. retention of biological activity in the presence of anti-serum to interferon gamma, interferon gamma, interferon alpha, or a combination of anti-sera to interferon alpha and gamma; and

(c) culturing the clone to produce the continuous cell line.

The reference relied upon by the examiner is:

Jones et al. (Jones), "Monocyte Cytotoxicity Factor (MCF) Production by Human T-cell Hybridoma," Immunobiol., vol. 167, abstract no. 365 (1984).

Grounds of Rejection

Claims 16-22, 24-25, 27-32, 34-35, and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

Claims 16-22, 24-25, 27-32, 34-35, and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention.

Claims 16-22, 24-25, 27-32, 34-35, and 42 stand rejected under 35 U.S.C. § 102 (b). As evidence of anticipation, the examiner relies upon Jones.

We reverse.

Background

The applicant describes the invention, as presently claimed, at page 9 of the specification as being directed to a continuous cell line, as well as a method of generating a continuous cell line, which produces a human monocyte cytotoxicity inducing factor (MCF) that is capable of inducing human monocytes to a cytotoxic state, wherein the cell line is produced by a process which includes the steps of immortalizing human T-cells to produce continuous cell clones, identifying a clone which produces the factor, and culturing the clone to provide the continuous cell line.

Discussion

The rejection under 35 U.S.C. § 112, first paragraph

Claims 16-22, 24-25, 27-32, 34-35, and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the full scope of the claimed invention.

To the extent that we understand the examiner's reasoning, this rejection is based on the examiner's determination that the claims read on subject matter not enabled by the specification. The examiner notes that pages 18 and 32-34 of the specification describe the identification of MCF-positive clones and urges that the claimed cell lines are identified as producing factor or factors that stimulate monocyte cytotoxicity, which are not necessarily the single factor described in the specification. The examiner thus concludes that the claimed invention is broader than the enabling disclosure. (Answer, page 8 and Supplemental Answer, page 4).

While we would agree that the claims on appeal are not necessarily limited to a cell line which produces a specific monocyte stimulating factor, on the record before us, the examiner has failed to make any of the factual findings which would reasonably support a rejection under the enablement requirement of 35 U.S.C. § 112, first paragraph. See In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). We, therefore, reverse the

rejection under 35 U.S.C. § 112, first paragraph.

The rejection under 35 U.S.C. § 112, second paragraph

Claims 16-22, 24, 25, 27-32, 34, 35, and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention.[1] The examiner urges that the terms “producing” “produces” “produced” and “secretes” refer to the production of MCF and the claims are unclear and do not particularly point out the invention since the cells are not capable of producing the factor in the absence of the mitogen and the claims do not reflect the presence of the mitogen. (Answer, page 10; Second Supplemental Answer, page 2).

The examiner has the initial burden of demonstrating indefiniteness of the claims. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion, this rejection falls by its own weight. The language of the claims indicates that the claimed cell line produces the factor. If a cell line is incapable of producing the described factor, it does not fall within the scope of the claims before us. We point out that it is well established that "definiteness of the language employed must be analyzed, not in a

[1] In setting forth the basis of this rejection the examiner states that the rejection of "claims 22-35" still stands. (Second Supplemental Answer, page 2). Manifestly, that reference constitutes an inadvertent error. Since each independent claim includes at least one form of the terminology on which the rejection is based, we have assumed the rejection is applicable to all of the appealed claims.

vacuum, but always in light of the prior art and of the particular application disclosure as it would be interpreted by one possessing the

ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). We note that the purpose of the second paragraph of Section 112 is to basically insure, with a reasonable degree of particularity, an adequate notification of the metes and bounds of what is being claimed. See In re Hammock, 427 F.2d 1378, 1382, 166 USPO 204, 208 (CCPA 1970). When viewed in light of this authority, we do not agree with the examiner that the metes and bounds of the rejected claims would not be capable of being determined when read in light of the specification and as one skilled in this art would interpret them. Here, one reading the claims in light of the specification would readily appreciate that the cells must be contacted with a mitogen in order to stimulate the production of the factor. However, the failure of the claims to explicitly state this information does not make the scope of the claims unclear. We, therefore, reverse the rejection of claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 112, second paragraph.

The rejection under 35 U.S.C. § 102(b)

In rejecting claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 102(b) as unpatentable over Jones, the examiner urges (Answer, page 8):

> [t]he reference teaches production of a human T cell hybridoma and cell lines, derived from Szeary's syndrome patients. The reference teaches the use of a mitogen and production of MCF, which inherently falls within the claimed weight ranges.

Appellant urges that Jones fails to provide an enabling disclosure and thus can not be prior art sufficient to render the appealed claims unpatentable. In support of this position, appellant provides the declaration of Dr. Jones filed July 20, 1989 during the prosecution of a related application. (Revised Principal Brief, Exhibit H). The examiner urges that these arguments and evidence are not persuasive since (Answer, page 11):

> [t]he declaration does not specifically address why the abstract does not teach a method of generating a continuous cell line that has the capacity of producing a factor.

Yet, our reading of the declaration would indicate that appellant has pointed to several deficiencies of the Jones abstract (Reply Brief, pages 24-25) which appear relevant to the question of whether Jones is enabling for that which it discloses.

One such point goes to the question of whether the disclosure that "a population of uniformly $OKT4^{+}$ lymphocytes was isolated by differential centrifugation over Percoll" (Jones, lines 7-8) is sufficient to permit those of ordinary skill in this art to actually isolate and identify those lymphocytes present which produce the MCF as required by the claimed invention. The Jones Declaration at page 3 states:

> The abstract does not teach how one would successfully carry out the Percoll gradient fractionation of T-cells so as to identify a fraction containing a subset of T-cells which produces MCF material.

This limited disclosure in Jones is contrasted with the specification which reasonably appears to provide detailed instructions at pages 23-34 as to how the cells lines are generated and provides specific information as to identifying and isolating those which produce MCF.

In addition, Dr. Jones indicates that the abstract erroneously indicates that the factor can be precipitated from the supernatant with 30-50% ammonium sulfate, which was subsequently found to result in the loss of virtually all of the associated biological activity which "would make it impossible to detect activity in any subsequent isolation steps and/or to obtain a final product with sufficient biological activity to be of use pharmacologically." (Exhibit H, Declaration, page 6). The examiner does not dispute this point. Yet, if appellant is correct that use of the precipitation step described by Jones would eliminate the very biological activity sought, then the reference cannot reasonably be considered to place that aspect of the invention in the hands of the public.

We agree with appellant that before a prior art disclosure can preclude an applicant from obtaining a patent, that prior art disclosure must contain an enabling disclosure. In re

Hoeksema, 399 F. 2d 269, 273, 158 USPQ 596, 600 ("[I]t is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be

such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.") (citation omitted). Here, the examiner has failed to come to grips with the specific points raised by appellant's arguments and the declaration evidence presented to demonstrate that the prior art relied upon by the examiner would not have been enabling. It is the initial burden of the patent examiner to establish that claims presented in an application for a patent are unpatentable. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). However, the burden on the examiner does not end there. Where, as here, the appellant provides arguments and evidence in support of patentability of the rejected claims, the examiner must step back and consider anew the question of whether the claims are properly rejected having weighed the evidence and arguments made of record in support of patentability against those in support of unpatentability. See In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 685-86 (Fed. Cir. 1986);
In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976); In re Piasecki, 745 F.2d 1468, 1471, 223 USPQ 785, 788 (Fed. Cir. 1984). On balance, we find the

arguments and evidence presented by appellant outweigh the arguments and facts provided by the examiner as to the question of whether Jones provides an enabling disclosure which would have placed the claimed invention in the hands of the public. Thus, we find that the examiner has failed to establish prima facie case of anticipation

within the meaning of 35 U.S.C. § 102(b). Therefore, the rejection of claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 102(b) is reversed.

SUMMARY

To summarize, the decision of the examiner to reject claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 112, first paragraph is reversed. The decision of the examiner to reject claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 112, second paragraph is reversed. The decision of the examiner to reject claims 16-22, 24, 25, 27-32, 34, 35, and 42 under 35 U.S.C. § 102(b) is reversed.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
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) BOARD OF PATENT

MARY F. DOWNEY Administrative Patent Judge	)	
	)	APPEALS AND
	)	
	)	INTERFERENCES
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DOUGLAS W. ROBINSON Administrative Patent Judge	)	
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